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U.S. DISTRICT COURT
DISTRICT OF MASS.

UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

PAUL BENNETT, On Behalf of Himself and All Others Similarly Situated, Plaintiff, vs. ALKERMES, INC., et al., Defendants.	No. 03-CV-12091-RCL CLASS ACTION
VINCENT RAGOSTA, On Behalf of Himself and All Others Similarly Situated, Plaintiff, vs. ALKERMES, INC., et al., Defendants.	No. 03-CV-12184-RCL CLASS ACTION

[Caption continued on following page.]

SOUTHERN ALASKA CARPENTERS RETIREMENT TRUST'S MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF ITS MOTION TO CONSOLIDATE CASES FOR ALL PURPOSES AND FOR AN ORDER REQUIRING PRESERVATION OF DOCUMENTS

BARRY FAMILY LP, On Behalf of Itself and All Others Similarly Situated, Plaintiff, vs. ALKERMES, INC., et al., Defendants.	Civil Action No. 03-CV-12243-RCL CLASS ACTION
JULIUS AND PHYLLIS WALTZER, On Behalf of Themselves and All Others Similarly Situated, Plaintiffs, vs. ALKERMES, INC., et al., Defendants.	Civil Action No. 03-CV-12277-RCL CLASS ACTION
DEBRA S. FOLKERTS, On Behalf of Herself and All Others Similarly Situated, Plaintiff, vs. ALKERMES, INC., et al., Defendants.	Civil Action No. 03-CV-12386-RCL CLASS ACTION
JAMES P. SLAVAS, On Behalf of Himself and All Others Similarly Situated, Plaintiff, vs. ALKERMES, INC., et al., Defendants.	Civil Action No. 03-CV-12471-RCL CLASS ACTION

I. INTRODUCTION

Presently pending in this district are six related securities class action lawsuits:

Abbreviated Case Name	Case Number	Date Filed
Bennett v. Alkermes , Inc., et al.	03-12091-RCL	10/29/03
Ragosta v. Alkermes, Inc., et al.	03-12184-RCL	11/06/03
Barry Family LP v. Alkermes, Inc., et al.	03-12243-RCL	11/13/03
Waltzer v. Alkermes, Inc., et al.	03-12277-RCL	11/17/03
Folkerts v. Alkermes, Inc., et al.	03-12386-RCL	11/25/03
Slavas v. Alkermes, Inc., et al.	03-12471-RCL	12/09/03

The Southern Alaska Carpenters Retirement Trust ("Movant" or "Proposed Lead Plaintiff") moves the Court to consolidate for all purposes the above-referenced actions and any related case later filed in this Court or otherwise transferred or removed to this Court pursuant to Rule 42 of the Federal Rules of Civil Procedure because each action is virtually identical and raises common questions of fact and law.

II. SUMMARY OF ACTIONS

These related class actions allege a common course of conduct by the same defendants in violation of §§10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act"), and Rule 10b-5 promulgated thereunder, 17 C.F.R. §240.10b-5. The actions name Alkermes, Inc. ("Alkermes" or the "Company") and a number of its senior executives[1] as defendants and are brought on behalf of all persons who purchased or otherwise acquired Alkermes securities between

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[1] Richard F. Pops, Robert A. Breyer, David A. Broecker, Michael J. Landine, James M. Frates and James L. Wright are the individual defendants named in each of the complaints.

April 22, 1999 and July 1, 2002 (the "Class Period"). ¶1.[2] Each action alleges that defendants sought to artificially inflate the value of their securities through materially false and misleading statements about the Company's New Drug Application ("NDA") to the Federal Drug Administration ("FDA") for Risperdal Consta, allowing defendants to reap insider trading proceeds of over $43 million and causing the Company to sell $200 million worth of its own securities. ¶¶6, 8, 13-14, 16-18.

Alkermes is a biopharmaceutical company focused on the development of controlled-release drug delivery technologies and their application to existing or new drug therapies. ¶2. Risperdal belongs to a class of compounds referred to as atypical antipsychotics, used in the treatment of schizophrenia. ¶22. The goal of a successful drug to treat schizophrenia is to inhibit and eliminate the mental, emotional, and behavioral disturbances associated with the disorder, with minimal side effects. ¶27. Risperdal Consta is administered by an intramuscular injection into the deep muscle tissue of the patient. ¶29. If approved by the FDA, Risperdal Consta would represent the first example of a sustained release or "depot" formation for biweekly administration, to mitigate patient compliance issues. ¶23.

Throughout the Class Period, defendants concealed the deficient nature of their manufacturing process and facilities, as well as serious safety issues and adverse side effects associated with use of Risperdal Consta. ¶7. Specifically, on April 22, 1999, Alkermes issued a press release stating that Alkermes and its joint venture partner Janssen Pharmaceutica ("Janssen") were proceeding into Phase III clinical trials of sustained release Risperdal. ¶34. This press release

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[2] Unless otherwise indicated, all paragraph references ("¶") are to the complaint filed in *Bennett v. Alkermes, Inc. et al.,* Case No. 03-12091-RCL, on October 29, 2003. Each of the other actions contains similar allegations.

also stated that Alkermes had completed scale-up and Phase III manufacturing activities at the expected commercial scale. *Id.* Defendants, however, concealed the fact that their facilities were wholly unable to commence or maintain commercial scale operations for the manufacture of Risperdal Consta or any other drug product. ¶36. Defendants also concealed quality issues with the Medisorb polymer used in the production of Risperdal Consta manufacturing lots. ¶37. Defendants decided to forego routinely conducting tests for molecular weight on Medisorb polymer lots to conceal the fact that Medisorb polymer production methods resulted in molecular weights with an unacceptably wide variation from lot to lot for use in production of sustained-release drug delivery systems. *Id.*

On February 16, 2000, Alkermes issued a press release announcing the private placement of $200 million in convertible subordinated notes. ¶39. News of this badly needed financing reassured investors that the Company's products were viable, and Alkermes shares spiked nearly 90% in value in the days following the announcement. ¶40.

On May 19, 2000, defendants filed for the grant of a patent entitled "Method for Preparing Microparticles Having a Selected Polymer Molecular Weight." ¶41. Defendants sought this new patented and proprietary process that would actually complicate the Risperdal Consta manufacturing process in order to conceal quality issues relating to variation in the manufacturing process for the Medisorb polymer. ¶44.

In September 2000, defendants' joint venture partner Janssen caused to be published a Review Article entitled, "A Risk-Benefit Assessment of Risperidone for the Treatment of Behavioural and Psychological Symptoms in Dementia." ¶46. The article signaled the acceptability of the safety and efficacy profile of the drug for the treatment of dementia in the elderly. *Id.* While the article was intended to disclose serious Risperdal side effects as a part of a risk-benefit

assessment, it actually concealed serious adverse cerebrovascular side effects in the elderly, contained in one or more Janssen studies cited as references to the article. ¶46.

On September 4, 2001, the Company issued a press release signaling that Alkermes was ready to manufacture Risperdal Consta. ¶¶50-51. Defendants again concealed that their facilities were, in fact, unable to begin commercial manufacturing of the product at the expected levels. ¶51. In the September 4, 2001 press release, defendants raised broad-based concerns about all antipsychotic medications, but concealed the special safety concerns that would accompany use of Risperdal when formulated using Medisorb technology for sustained release. ¶52.

On October 30, 2001, the Company issued a press release claiming its current manufacturing facility was fully equipped to support launch quantities and to meet early demand projected for long-acting Risperdal. ¶57. Despite these assertions, defendants remained wholly unable to begin commercial manufacturing of the product at all expected levels. ¶58. The October 30, 2001 press release also stated that Alkermes had committed to expand production capacity in exchange for guaranteed financial payments from its joint venture partner Janssen. ¶57. Defendants' claims were false and misleading because they failed to point out that the costs of the expansion project were to be borne entirely by defendants and, after commercialization, were to come out of defendants' royalty revenues. ¶59.

On February 26, 2002, the Company issued a press release announcing the submission of a new drug application ("NDA") for Risperdal Consta by Johnson & Johnson Pharmaceutical Research & Development ("Johnson & Johnson"), which conducted the clinical-development program. ¶61. The press release also stated that the use of Risperdal Consta did not compromise patient safety. ¶¶61-62. This press release was false and misleading since Risperdal Consta cannot

be removed once injected and there is no way to discontinue delivery of the drug in patients once they are afflicted with adverse side effects. ¶62.

Moreover, safety concerns related to Risperdal Consta, including cerebrovascular effects in elderly patients, extrapyramidal symptoms, QT interval prolongation and diabetes, went unreported to worldwide regulatory authorities for long periods, in some cases for studies completed well before the beginning of the Class Period, and negatively impacted the regulatory review process. ¶¶7, 71-82. Defendants knew that for one or more reasons related to the known but unmet manufacturing, safety or efficacy requirements for the drug, the NDA for Risperdal Consta would not be approved on July 1, 2002. ¶82.

On July 1, 2002, both the Company and Johnson& Johnson issued press releases announcing that Johnson & Johnson had received a non-approvable letter from the FDA for Risperdal Consta. ¶¶64-65. The Johnson & Johnson press release stated that the FDA had not raised any significant concerns regarding the manufacturing process. ¶65. Defendants themselves failed to note that they were still at the earliest stage of converting their facility into the highly automated commercial manufacturing facility that would be necessary for commercial production. ¶66.

As a result of the July 1, 2002 announcement of a non-approvable letter for Risperdal Consta, Alkermes' stock price dropped over a two-day period from a high of $16.01 per share to a low of $4.04 per share – a drop of over 74%. ¶67.

III. ARGUMENT

A. This Court Should Consolidate the Six Related Lawsuits for Purposes of Efficiency

Rule 42(a) of the Federal Rules of Civil Procedure allows this Court to order consolidation of separate actions. When actions involving a common question of law or fact are pending before the court, it may order a joint hearing or trial of any or all the matters at issue in the actions; it may order

all the actions consolidated; and it may make such orders concerning proceedings therein as may tend to avoid unnecessary costs or delay.

This Court has the discretion to consolidate cases relating to the same subject matter and any related case later filed in this Court or otherwise transferred or removed to this Court. *Seguro de Servicio de Salud de Puerto Rico v. McAuto Sys. Group, Inc.*, 878 F.2d 5, 8 (1st Cir. 1989); *In re PRI Automation, Inc. Sec. Litig.*, 145 F. Supp. 2d 138, 140 (D. Mass. 2001).

The six actions pending before this Court present virtually identical factual and legal issues, and each names Alkermes and the same officers and directors as defendants. All six lawsuits are based on the same facts and involve the same subject matter. The same discovery will be relevant to all lawsuits. Each complaint alleges that Alkermes and its executive officers made materially false and misleading public statements in news releases, SEC filings, and in meetings with securities analysts. Each complaint alleges that the complained about statements failed to disclose, *inter alia*, critical material information regarding the Company's development of Risperdal Consta, an atypical antipsychotic, used in the treatment of schizophrenia. Each complaint alleges that the defendants continued to make these misrepresentations despite, as alleged in each of the complaints, having knowledge of material problems with the Company's NDA for Risperdal Consta.

Each of the six actions alleges violations of §§10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder. The following common questions of law and fact are present in all six actions:

1. Whether the federal securities laws were violated by defendants' acts as alleged herein;

2. Whether the statements disseminated to the investing public and securities markets by defendants misrepresented and/or omitted material facts necessary to make the statements not misleading;

3. Whether defendants knew or had reasonable grounds to believe that their statements were false and misleading;

4. Whether the market price of Alkermes' securities during the Class Period was artificially inflated due to the misrepresentations and/or non-disclosures alleged; and

5. The extent of damages suffered by members of the class.

Because these lawsuits concern virtually identical legal and factual issues and name similar defendants, Movant requests that this Court consolidate these six actions into one action for all purposes.

Courts have consistently recognized that securities class actions are, in particular, ideally suited to consolidation pursuant to Fed. R. Civ. P. 42, because their unification expedites pretrial proceedings, reduces case duplication, avoids the harassment of parties and witnesses from inquiries in multiple proceedings, and minimizes the expenditure of time and money by all persons concerned. *In re Equity Funding Corp. of Am. Sec. Litig.*, 416 F. Supp. 161, 176 (C.D. Cal. 1976) (citing *Garber v. Randell*, 477 F.2d 711, 714 (2d Cir. 1973)). Consolidating multi-shareholder class action suits simplifies pretrial and discovery motions, class action issues, and clerical and administrative management duties. Moreover, consolidation will reduce the confusion and delay that may result from prosecuting related class action cases separately. *Id.*

Consolidation of related actions is proper and appropriate even if the defendants named are not identical and the alleged class periods differ. In granting a motion for consolidation, the court in *Lloyd v. Industrial Bio-Test Laboratories, Inc.*, 454 F. Supp. 807 (S.D.N.Y. 1978), stated:

> Indeed, this action and *Desimone* differ only in that (1) plaintiff here purchased Syntex options rather than Syntex common stock, (2) the putative class period here is slightly shorter than that in *Desimone*, and (3) three individual defendants named in *Desimone* are not named here. The legal and factual issues in both actions are otherwise identical. We, therefore, conclude that the two suits involve "common question[s] of law or fact."

Id. at 812 (citation omitted). Similarly, in *In re Food Fair Sec. Litig.*, 465 F. Supp. 1301 (J.P.M.L. 1979), the Judicial Panel on Multidistrict Litigation found that related cases which include class action allegations, which differed only in purported length of the class period, involve common questions of law and fact and may properly be transferred and consolidated.

B. The Private Securites Litigation Reform Act Requires that the Question of Consolidation Be Decided Prior to the Determination of the Appointment of Lead Plaintiff

On December 22, 1995, Congress enacted the Private Securities Litigation Reform Act of 1995 ("PSLRA" or the "Reform Act"), which, among other things, provides for consolidation of actions. The Reform Act provides, in pertinent part:

> If more than one action on behalf of a class asserting substantially the same claim or claims arising under this title has been filed, and any party has sought to consolidate those actions for pretrial purposes or for trial, the court shall not make the determination [of appointment of lead plaintiff under §21D(a)(3)(B)(i)] until after the decision on the motion to consolidate is rendered.

Exchange Act §21D(a)(3)(B)(ii) (as added by the PSLRA), Pub. L. No. 104-67, §101(a)), 15 U.S.C. §78u-4(a)(3)(B)(ii).

The PSLRA sets up a two-step process where more than one action on behalf of a class asserting virtually the same claims has been filed. The Court "shall" first decide the consolidation issue and thereafter decide the lead plaintiff issue "[a]s soon as practicable" after the consolidation motion has been decided. *Id.*

Plaintiffs urge the Court to resolve the consolidation motion as soon as practicable and consolidate these six related actions under the lowest case number. A prompt determination is

reasonable and warranted under Fed. R. Civ. P. 42(a), given the common questions of fact and law presented by the six related actions now pending in this district.

C. This Court Should Order the Preservation of Documents

Through this motion, Southern Alaska Carpenters Retirement Trust also requests that the Court order the preservation of documents relating to the consolidated actions in accordance with 15 U.S.C. §78u-4(b)(3)(C)(i) both prior to and after the filing of any motion to dismiss. In complex securities cases involving companies with numerous employees, such an order is appropriate and will prevent the loss of key documents, whether through inadvertence or otherwise.

IV. CONCLUSION

For the above reasons and in order to promote judicial economy, Movant respectfully requests that the Court consolidate the above-referenced related actions and order the preservation of documents.

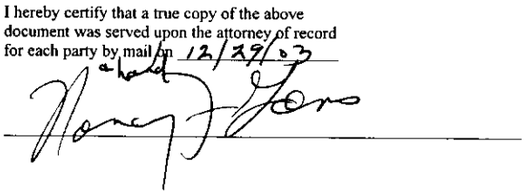
DATED: December 29, 2003

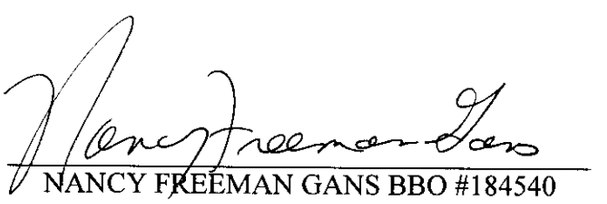
Respectfully submitted,

MOULTON & GANS, P.C.

CERTIFICATE OF SERVICE

I hereby certify that a true copy of the above document was served upon the attorney of record for each party by mail on 12/29/03





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